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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,237	07/14/2003	Jorgen K. Smedegaard	6520.200-US	5828

23650 7590 12/15/2005

NOVO NORDISK, INC.  
PATENT DEPARTMENT  
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EXAMINER

AHMED, AAMER S

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/619,237	<b>Applicant(s)</b> SMEDEGAARD, JORGEN K.	
	<b>Examiner</b> Aamer S. Ahmed	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-23 is/are rejected.
- 7) ☒ Claim(s) 20,21 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/27/03 11/10/03</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 27, 2005.

#### ***Claim Objections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 recites the limitation "infusion device" in line 28. There is insufficient antecedent basis for this limitation in the claim.

The term "bedtime" in claim 21 is a relative term, which renders the claim indefinite. The term "bedtime" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are the structure of the delivery device.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al U.S. Patent Number 5,848,991. Gross et al discloses a method for treatment of a patient suffering from a condition, comprising the steps of providing a delivery device (2) adapted to deliver an amount of a drug beneficial for the treatment of the condition, establishing at a given time a fluid communication between the delivery device and the body of the patient, delivering a therapeutic amount of the drug during a period of approximately 7-9 hours (col. 4 line 55) and disconnecting the fluid communication between the delivery device and the body of the patient after approximately 7-9 hours, and wherein the fluid communication is provided by arranging the delivery device against a skin surface of the patient (see abstract) and the fluid communication is disconnected by removing the infusion device from the patient, and wherein the fluid communication is established at bedtime, the drug being infused substantially corresponding to a period of sleep; and wherein the drug is insulin-containing (col. 4 line 55 and col. 6 line 56).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 20050043863 A1 Ali, Irfan Z. et al.  
US 5169390 A Athayde; Amulya L. et al.  
US 20030065284 A1 Briggs, Dennis A.  
WO 9932174 A1 CHO, OK KYUNG  
US 6589229 B1 Connelly; Robert I. et al.  
US 4340048 A Eckenhoff; James B.  
US 4552561 A Eckenhoff; James B. et al.  
US 4494950 A Fischell; Robert E.  
US 4954344 A Gale; Robert M.  
WO 2055128 A2 GONNELLI, ROBERT R et al.  
US 6939324 B2 Gonnelli; Robert R. et al.  
US 5527288 A Gross; Joseph et al.  
US 5997501 A Gross; Joseph et al.  
US 20040181204 A1 Jasperson, Keith E. et al.  
US 6302869 B1 Klitgaard; Peter Christian  
US 2605765 A PAUL KOLLSMAN  
US 2605765 A PAUL KOLLSMAN  
US 5957895 A Sage; Burton H. et al.  
US 6074369 A Sage; Burton H. et al.  
US 6558351 B1 Steil; Garry M. et al.  
US 5858001 A Tsals; Izrail et al.  
US 6280148 B1 Zengerle; Roland et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.


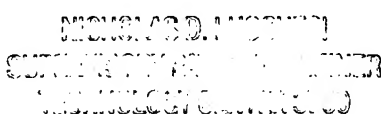
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed

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